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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,647	03/02/2004	Robert E. Fischell	CRD-946 DIV	3069

27777 7590 04/19/2005

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EXAMINER	
DAVIS, DANIEL J	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,647	FISCHELL ET AL.	
	Examiner	Art Unit	
	D. Jacob Davis	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 41 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lorentzen Cornelius et al. (US 6,068,634). Lorentzen discloses a primary stenting system (Fig. 9) comprising a flexible guidewire (Col. 5, line 60), a balloon catheter having an inflatable balloon 114, a polyurethane distal tip 117 (Col. 4, lines 41-45), a lumen 118, a stent 120, and proximal and distal elastomeric bands 122 and 124. The tip is inherently flexible to some degree since it must safely maneuver tortuous passage. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the polyurethane tip flexible so that it does not damage the vessels as it advances through the tortuous passage.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen in view of Fischell et al. (US 5,792,144). Lorentzen discloses a tapered tip 117 but fails to disclose the length of the tip or the exact degree of taper. Nevertheless, Fischell discloses a tapered tip having a tapered slope of less than 4 degrees (Col. 6, line 23) and a length that is greater than 10 mm to penetrate a stenosis (Col. 5, line 21). Although the patent does not disclose the length of the tip being greater than 20 mm, such a length would also be obvious to one of ordinary skill in the art to effectively penetrate a stenosis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Lorentzen's tip 117 greater than 10 mm as taught by Fischell to effectively penetrate a stenosis, and even greater than 20 mm which also would effectively penetrate a stenosis. Moreover, it would have been obvious to one of ordinary skill in the art to adjust Lorentzen's tapered tip to have a slope of less than 4 degrees as taught by Fischell to also penetrate a stenosis.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen in view of Wang et al. (US 6,221,097). Lorentzen discloses elastomer bands but is silent regarding a lubricous coat. Nevertheless, Wang discloses elastomer sleeves that are coated with a lubricant (Col. 2, lines 2-20) to facilitate the release of the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to lubricate Lorentzen's bands 122 and 124 as taught by Wang to facilitate the release of the stent.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen in view of Drewes, Jr. et al. (US 5,300,048). Lorentzen discloses bands 122 and 124 made of an elastomer, but fails to disclose a high density material included in the elastomer bands to increase radiopacity. Nevertheless, Drewes discloses that high density materials such as tungsten, may be added to an elastomeric material to increase radiopacity (Col. 2, lines 15-21). The increased radiopacity of the bands helps monitor catheter location. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a high density material to Lorentzen's bands 122 and 124 as taught by Drewes to increase radiopacity, in turn helping to monitor catheter location.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (571) 272-4693. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DJD

GLENN K. DAWSON
PRIMARY EXAMINER